

UNITED STATES PATENT APPLICATION
FOR
APPARATUS AND METHOD FOR CONNECTING SPINAL VERTEBRAE

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APPARATUS AND METHOD FOR CONNECTING SPINAL VERTEBRAE

Cross Reference to related Co-Pending Applications

This application is a continuation in part of U.S. application Serial No. 10/364847 filed
5 on February 11th, 2003 and entitled APPARATUS AND METHOD FOR THE
REPLACEMENT OF POSTERIOR VERTEBRAL ELEMENTS the contents of which
are expressly incorporated herein by reference.

Field of the Invention

10 The present invention relates to an apparatus and a method for connecting spinal
vertebrae, and more particularly to an apparatus and a method that connects spinal
vertebrae while preserving spinal stability and mobility.

Background of the Invention

15 The human spine 29 comprises individual vertebrae 30 that interlock with each other to
form a spinal column, shown in FIG. 1A. Referring to FIGS. 1B, 1C, and 1D, each
vertebra 30 has a cylindrical bony body (vertebral body) 32, two pedicles 48 extending
from the vertebral body 32, a lamina 47 extending from the pedicles 48, three winglike
projections (two transverse processes 33, 35 extending from the pedicles 48 and one
20 spinous process 34 extending from the lamina 47), pars interarticularis 36, two superior
facets 46 extending from the pedicles 48 and two inferior facets 45 extending from the
lamina 47. The pars interarticularis 36 connects the superior 46 and inferior 45 facets on
either side of the spinous process 34. The bodies of the vertebrae 32 are stacked one on
top of the other and form the strong but flexible spinal column. The spinous process 34,
25 lamina 47, pars interarticularis 36, superior facets 46, inferior facets 45, transverse
processes 33, and pedicles 48 are positioned so that the space they enclose forms a tube,
i.e., the spinal canal 37. The spinal canal 37 houses and protects the spinal cord and other
neural elements. A fluid filled protective membrane, the dura 38, covers the contents of
the spinal canal. The spinal column is flexible enough to allow the body to twist and
30 bend, but sturdy enough to support and protect the spinal cord and the other neural
elements.

The vertebrae 30 are separated and cushioned by thin pads of tough, resilient fiber known as inter-vertebral discs 40. Inter-vertebral discs 40 provide flexibility to the spine and act as shock absorbers during activity. There is a small opening (foramen) 42 between each vertebra 30, through which nerves 44 pass and go to different body parts. When the vertebrae are properly aligned the nerves 44 pass through without a problem. However, when the vertebrae are misaligned or a constriction 45 is formed in the spinal canal, the nerves get compressed 44a and may cause back pain, leg pain or other neurological disorders. Disorders of the spine that may cause misalignment of the vertebrae or constriction of the spinal canal include spinal injuries, infections, tumor formation, herniation of the inter-vertebral discs (i.e., slippage or protrusion), arthritic disorders, and scoliosis. In these pathologic circumstances, surgery may be tried to either decompress the neural elements and/or fuse adjacent vertebral segments. Decompression may involve laminectomy, discectomy, or corpectomy. Laminectomy involves the removal of part of the lamina 47, i.e., the bony roof of the spinal canal. Discectomy involves removal of the inter-vertebral discs 40. Corpectomy involves removal of the vertebral body 32 as well as the adjacent disc spaces 40. Laminectomy and corpectomy result in central exposure of the dura 38 and its contents. An exposed dura 38 puts the neural elements and spinal cord at risk from direct mechanical injury or scarring from overlying soft tissues. Scarring is considered a major cause for failed back syndrome in which patients continue to have back and leg pain after spinal surgery. Current methods to decrease the risk of developing this syndrome include covering the dura with fat harvested from the patient's subcutaneous tissues or using a synthetic material. However, no material as yet has been used that completely or significantly prevents scarring of the dura and nerve roots after spine surgery in humans.

Furthermore, laminectomy predisposes the patient to instability through the facet joints and may lead to post-laminectomy kyphosis (abnormal forward curvature of the spine), pain, and neurological dysfunction. Therefore the surgeon needs to stabilize the spine after laminectomy procedures and after corpectomy. One spine stabilization method is fusion. Fusion involves the fixation of two or more vertebrae. Fusion works well

because it stops pain due to movement of the intervertebral discs 40 or facets 45, 46, immobilizes the spine, and prevents instability and or deformity of the spine after laminectomy or corpectomy. However, spinal fusion limits spinal mobility. Maintaining spinal mobility may be preferred over fusion in some cases to allow more flexibility of the spine and to decrease the risk of junction problems above and below the level of the fixation due to increased stress.

An arthritic facet joint may also cause back pain. Since the majority of the motion along the spine occurs at the facet joints, fusing the diseased facet would often relieve pain but again at a high cost of fusing across at least one spinal segment thus preventing motion and effectively increasing stresses at the adjacent facet joints. Increased stresses predispose facet joints to accelerated arthritis, pain, and instability requiring additional surgery to fuse these levels. This cyclic process results in an overall decreased mobility of the spine. Therefore, it is an attractive alternative to attempt to replace the diseased facet without resorting to fusion, thus avoiding significant limitation in mobility of the spine. The obvious solution would be to replace the opposing surfaces of each facet to preserve motion between the surfaces. However, any efforts to replace the facets at their natural location necessitate destroying the facet capsule and risks producing an unstable joint. Therefore, it is desirable to achieve spine stabilization that preserves mobility, and does not cause tissue scarring or destroy the facet capsule. It is also desirable to be able to implant the stabilization device percutaneously utilizing minimally invasive surgery.

Summary of the Invention

In general, in one aspect, the invention features an orthopedic implantable device articulately connecting a first spinal vertebra to an adjacent second spinal vertebra. The orthopedic implantable device includes a pair of first components adapted to be attached to locations left and right of a midline of the first vertebra and a pair of second components adapted to be attached to locations left and right of a midline of second vertebra. Each of the first components comprises a body and a male articulation member attached to the first component body and each of the second components comprises a

body and a female articulation member attached to the second component body. The first components are articulately connected to the second components by engaging the male articulation members to the female articulation members, thereby articulately connecting the first vertebra to the second vertebra along lines left and right of the mentioned
5 midlines, respectively.

Implementations of this aspect of the invention may include one or more of the following features. The male articulation member may comprise a hook and the female articulation member may comprise a loop. The first component body may further comprise at least
10 one female articulation member and the second component body may further comprise at least one male articulation member. The locations left and right of the midlines of the first and second vertebrae are selected from a group including a pedicle, transverse processes, facets, lamina, pars interarticularis, and vertebral body. The body of the first component may be attached to first and second pedicles of the first vertebra and the body
15 of the second component may be attached to first and second pedicles of the second vertebra, respectively. The first and second components may be attached to the first and second vertebrae, respectively, via screws, wires, or hooks. The first component may be articulately connected to the second component via a hinge. The first and second components may have adjustable length and the length may be adjusted between 10 and
20 200 millimeters. The first and second components may be made of metal, plastic, ceramic, bone, polymers, composites, absorbable material, biodegradable material, and combinations thereof. The female articulation members may be formed within the second component bodies. The male articulation member may be a hook and the female articulation member may be a bar connecting opposite sides of a cavity formed within a
25 bottom surface of the body.

In general, in another aspect, the invention features a spine stabilization method articulately connecting a first vertebra to a second vertebra including the following steps. First providing a pair of first components and attaching the first components to locations
30 left and right of the midline of the first vertebra, respectively. Each first component comprises a body and a male articulation member attached to the body. Next, providing

a pair of second components and attaching the second components to locations left and right of the midline of the second vertebra, respectively. Each second component comprises a body and a female articulation member. Finally, articulately connecting the first component to the second component by engaging the male articulation members to the female articulation members.

In general, in another aspect, the invention features a spine stabilization method connecting a first vertebra to a second vertebra including the following steps. First attaching first and second screws to first and second locations left and right of a midline, of the first vertebra, respectively. Next attaching third and fourth screws to first and second locations left and right of a midline of the second vertebra, respectively. Next providing a pair first components and a pair of second components. Each of the first components comprises a body and a male articulation member attached to the first component body. Each of the second components comprises a body and a female articulation member attached to the second component body. Next articulately connecting the first components to the second components by engaging the male articulation members to the female articulation members. Next attaching the bodies of the pair of first components to the first and second locations of the first vertebra via the first and second screws, respectively. Next, attaching the bodies of the pair of second components to the first and second locations of the second vertebra via the third and fourth screws, respectively. Finally, tightening of all said screws. This aspect of the invention may further include before attaching the bodies of the first and second components adjusting the length of the bodies of the first and second components.

Among the advantages of this invention may be one or more of the following. The implantable spinal stabilization device stabilizes the spine, while allowing the patient to retain spinal flexibility by preserving motion between adjacent vertebrae. This spinal stabilization device may be implanted percutaneously along the sides left and right of the spine utilizing minimally invasive surgery, i.e., without the need to make a large midline incision and stripping the erector spinae muscles laterally. There is also no need to remove the posterior elements of the vertebrae such as the spinous processes and lamina.

The spinal stabilization device may be used for the treatment of a multitude of spinal disorders including facet arthritis and spinal stenosis. The implantable device has a compact structure and low profile.

- 5 The details of one or more embodiments of the invention are set forth in the accompanying drawings and description below. Other features, objects and advantages of the invention will be apparent from the following description of the preferred embodiments, the drawings and from the claims.

10 **Brief Description of the Drawings**

Referring to the figures, wherein like numerals represent like parts throughout the several views:

FIG. 1A is a side view of the human spinal column;

- 15 FIG. 1B is an enlarged view of area A of FIG. 1A;

FIG. 1C is an axial cross-sectional view of a lumbar vertebra;

FIG. 1D is a perspective view of a lumbar vertebra;

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FIG. 2 is a schematic posterior view of an implantable spine stabilization device according to this invention;

FIG. 3 is a posterior view of a spine stabilization component of the implantable spine
25 stabilization device of FIG. 2;

FIG. 4 is a perspective view of a lumbar vertebra with resected spinous process, lamina, and facet joints and the stabilization component of FIG. 3 attached to its pedicles ;

- 30 FIG. 4A is a cross-sectional view of FIG. 3 along AA' plane;

FIG. 5 is a perspective view of the spine stabilization component of FIG. 3;

FIG. 5A is a cross-sectional view of FIG. 3 along BB' plane;

5 FIG. 6 is a cross-sectional side view of the spine stabilization device of FIG. 2 along
midline 102;

FIG. 7 is a posterior view of a spine stabilization component without a tail segment;

10 FIG. 8 is a flow diagram depicting the method of applying the implantable spine
stabilization device of this invention; and

FIG. 9 is a schematic posterior view of another embodiment of an implantable spine
stabilization device according to this invention.

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Detailed Description of the Invention

Referring to FIG. 2, an implantable spine stabilization device 100 connects vertebra 92 to
20 adjacent vertebra 94 and vertebra 94 to adjacent vertebra 96. The spine stabilization
device 100 includes modular components 110, 120, and 130. Modular components 110,
120, and 130 have circular ends 110a and 110b, 120a and 120b, 130a and 130b,
respectively, that attach to pedicles 92A, 92B, 94A, 94B, 96A, and 96B of vertebra 92,
94 and 96, respectively, via pedicle screws 111a, 111b, 121a, 121b, 131a, and 131b,
25 respectively. Modular components 110, 120, and 130 replace the resected laminae, pars
interarticularis, facets and spinous processes of the vertebra 92, 94, and 96, respectively.
Modular component 110 is articulately connected to component 120 along the midline
102 of the device 100 and the corresponding vertebrae 92 and 94, shown in FIG. 6.
Similarly modular component 120 is articulately connected to component 130. Additional
30 modular components may be added to extend the spine stabilization device 100 in either
caudad 272 or cephalad 270 directions. The modular structure of the spine stabilization

device 100 allows a surgeon to replace laminas, facets, pars interarticularis, and spinous processes over any distance and orientation along the entire spine 29.

Referring to FIG. 3, modular component 110 comprises a lamina 114, two circular ends 5 110a, 110b extending laterally from opposite sides of the lamina 114, a tail segment 118 extending from the lower portion of the lamina 114, and a spinous process 116 protruding posteriorly from the top surface of the lamina 114. The lamina 114 has a width 81 and a length 82 that depend upon the distance between the pedicles 92A and 92B and the length of the vertebra 92, respectively. The length 83 of the tail segment 118 depends upon the 10 intervertebral distances. In one example, the width 81 is in the range between 20 millimeters and 80 millimeters, length 82 is in the range of 10 millimeters and 80 millimeters, length 83 is in the range of 4 millimeters and 60 millimeters and height 84 is in the range of 4 millimeters and 30 millimeters. Width 81, length 82, length 83 and height 84 have different values for the different type of vertebrae, including lumbar, 15 thoracic, sacral and cervical.

Referring to FIG. 3 and FIG. 5, pedicle screw 111b comprises a body portion 140, a first head portion 142, a second head portion 144, and a head 146. The body portion 140 of the pedicle screw 111b has helical threads on its exterior surface and screws into the 20 vertebral body 32 through the pedicle 92B. A hexagonal screwdriver (not shown) is inserted into a slot 148 formed on the head 146 of the pedicle screw 111b and is used to drive the screw 111b into the vertebral body 32. The first head portion 142 is directly above the body portion 140 and has a smooth or serrated outer surface 143 for receiving the circular end 110b of modular component 110. End 110b has an aperture 152b that 25 allows end 110b to slide over the pedicle screw 111b. The second head portion 144 has a threaded outer surface for receiving locking nut 112b. Locking nut 112b slides over the head 146 of the pedicle screw 111b and screws around the threaded outer surface of the second head portion 144, thus securely attaching the circular end 110b to pedicle screw 111b.. In one example, pedicle screw 111a has a length 220 of 57 millimeters and a 30 diameter 222 of 6.5 millimeters.

Referring to FIG. 4 and FIG. 4A, the cross-section of lamina 114 along AA' has a U-shape and the roof 114c of the lamina (top of U-shape) is elevated above the spinal canal 37. The sides 114a and 114b of the lamina 114 run first at a gentle slope downwards about 5 degrees and then drop more sharply at about 80 degrees to get to the pedicles 92A and 92B, respectively. The U-shape form of the lamina 114 provides space between the spine stabilization device 100 and the spinal canal 37 and is also designed to clear the facets 46 laterally, in case they were not previously resected. This arrangement covers the central spinal canal and protects the neural elements from scar tissue formation or mechanical damage. The lamina 114 has a flared lower portion that extends into the tail segment 118.

In the embodiment of FIG. 4A the width 81 of the lamina 114 is extended or contracted via mechanism 90. In this embodiment the lamina 114 comprises a first segment 92 and a second segment 94. Segment 94 is allowed to slide in the lateral direction 86 and can rotate around the axis 87. The lateral motion of segment 94 allows the adaptation of the modular component 110 to vertebrae with various pedicle distances. The rotation of segment 94 around the axis 87 allows accurate positioning of the circular end 110b over the pedicle screw 111b and accommodates pedicles that are not perfectly aligned in the cephalo-caudad direction. Segments 94 and 92 have overlapping elongated slots 184A and 184B, respectively, extending through the thickness of the corresponding segment. A housing 182 slides over the overlapping segments 92 and 94. Housing 182 has an elongated slot 186 that runs through the thickness of the housing 182 and is aligned with the elongated slots 184A and 184B. The position of the overlapping segments 92 and 94 and the housing 182 is secured via a screw 188 that is threaded through the elongated slots 184A, 184B, and 186. In one example, the width 81 of the lamina 114 is 40 millimeters and it can be increased or decreased up to 8 millimeters via the two sliding mechanisms 90. Circular ends 110a, 110b have apertures 152a, 152b, respectively. Apertures 152a and 152b have serrated inner surfaces for receiving a pedicle screw with matching longitudinal serrations 143, shown in FIG. 5. The top and/or bottom surfaces of circular ends 110a, 110b have radial extending grooves 88 that match the grooves 89 of the locking nuts 112a, 112b.

Referring to FIG. 5 and FIG. 5A, the posteriorly protruding spinous process 116 includes a cavity 115 formed in the bottom surface of the lamina 114 within the spinous process 116. Inside the cavity 115 there is a horizontally extending bar 117 attached to opposite
5 cavity walls 115a, 115b. Referring to FIG. 6, the end of the tail segment 118 of modular component 110 forms a hook 119. Hook 119 engages around the horizontal bar 117 of the adjacent modular component 120 and forms an articulated connection between the two modular components 110 and 120. The cavity 115 is contoured to allow smooth gliding of the outer surface 118a of the tail segment 118 around the horizontal bar 117.

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Referring to FIG. 7, a modular component 140 without the tail segment 118 is implanted to the pedicles on the vertebra that is below but adjacent to the lowest (in the caudad direction 272) level that underwent either a laminectomy or facetectomy. This vertebra will still have its natural spinous process and ligamentous attachment to the next lower
15 vertebra. This vertebral level will therefore provide stability to the end of the stabilization assembly 100 since this vertebral level will have preserved facets and ligamentous attachments.

Referring to FIG. 8, a method 400 of using the spine stabilization device 100 comprises
20 the following steps. Opening an incision in the patient's back, and exposing first and second vertebrae, the vertebra that is immediately above but adjacent to the first vertebra (cephalad direction), and the vertebra that is immediately below but adjacent to the second vertebra (caudad direction) (405). Performing laminectomy and/or facetectomy posteriorly of the first and second vertebrae (410). Placing pedicle screws within the
25 pedicles of the first and second vertebra, the vertebra immediately above the first vertebra, and the vertebra immediately below the second vertebra (420). Engaging a first modular component to a second modular component. In one example, the modular components are as shown in FIG. 3. Placing the apertures of the two circular ends 110a, 110b of the first modular component over the two contralateral pedicle screws on the first
30 vertebra, and adjusting the length and orientation of the two end segments 94 of the lamina (430). Placing the apertures of the two circular ends 110a, 110b, of the second

modular component over the two contralateral pedicle screws on the second vertebra, and adjusting the length and orientation of the two end segments 94 of the lamina (440). Engaging a third modular component without a tail segment, as shown in FIG. 7, to the tail of the second modular component, placing the apertures of the two circular ends 5 110a, 111ab, of the third modular component over two contralateral pedicle screws on the vertebra that is immediately below the second vertebra, and adjusting the length and orientation of the two end segments 94 of the lamina (450). Engaging a fourth modular component to the first modular component, placing the apertures of the two circular ends 110a, 110b, of this fourth modular component over the two contralateral pedicle screws 10 on the vertebra that is immediately above the first vertebra, and adjusting the length and orientation of the two end segments 94 of the lamina (455). Tightening of the nuts over the pedicle screws down on the circular ends (460) and closing of the incision in the patient's back (470).

15 Referring to FIG. 9, an implantable spine stabilization device 200 connects vertebra 92 to adjacent vertebra 94. The spine stabilization device 200 includes modular components 210, 220, 230 and 240. Modular components 210, 220, 230 and 240 have circular ends 211, 221, 231, and 241, respectively, that attach to pedicles 92B, 94B, 92A, 94A, of vertebrae 92 and 94, respectively, via pedicle screws 212, 222, 232, and 242 20 respectively. Modular component 210 is articulately connected to component 220 along a line 201 left of the midline 202 of vertebrae 92 and 94. Modular component 230 is articulately connected to component 240 along a line 203 right of the midline 202 of vertebrae 92 and 94. Additional modular components may be added left and/or right of the midline 202 to extend the spine stabilization device 200 in either caudad 272 or 25 cephalad 270 directions. Modular components 210 and 230 are articulately connected to modular components 220 and 240, respectively with an articulation mechanism similar to the one of FIG. 2, and FIG. 6. Modular components 210, 230 have hook tail segments 119 similar to the one described in FIG. 6. Modular components 220 and 240 have a cavity 115 with a bar 117 extending across opposite cavity walls, thereby forming a loop 30 similar to the one described in FIG. 5 and FIG. 5A. Hook-shaped tail segment 119 engages around bar 117 into the loop formed in cavity 115, thereby articulately

connecting modular component 210 and 230 to modular components 220 and 240, respectively. Modular components 210, 220, 230 and 240 may have adjustable length. The length of the modular components may be adjusted to be in the range of 10 millimeters to 200 millimeters.

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Other embodiments are within the scope of the following claims. For example, the articulation mechanism between the modular components may be a hinge. There may be more than one articulation mechanisms medial or lateral to the medial line 102 on a given vertebra, and/or medial to both the natural facet joints. The ends of the modular components may be secured to pedicle screws via connectors. The ends of the modular components may be attached to the vertebrae via hooks. Other locations where screws, wires, or hooks may be anchored for attaching the stabilization device of this invention include the transverse processes 33, 35, the vertebral body 32, and the lamina 47. The modular components may be solid without adjustable ends. Modular components 110,120,130 and 140 may be manufactured from a variety of materials including among others stainless steel, titanium, nickel, composites, ceramics, plastic, bone, bioabsorbable material or combination thereof. Pedicle screws may be manufactured from a variety of materials including among others stainless steel, titanium, gold, silver ceramics, plastic, bioabsorbable material, or alloys thereof.

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Several embodiments of the present invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

25 What is claimed is:

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